CONTRIBUTION

FROM

NATIONAL INSTITUTES OF HEALTH--U.S.A

Principles and Methods Used for Formulating National Policies on Biomedical Research

December 1974

Introduction

The biomedical research network. The formulation of national policies on biomedical research in the United States depends on decisions made in both the Executive and Legislative Branches of the Federal government, in centers of biomedical research in university and nonprofit settings, in industry, and in professional and health constituency groups. A national biomedical research network is formed by the commitments of these institutions to informal and contractual relationships, by flows of program stimuli and financial support, by movements of personnel, and by the exchange of research findings. The National Institutes of Health (NIH)--the nearest equivalent in the U.S. to a medical research council--is the most concentrated focus of program planning and financial support in the network.

The division of labor. Around $4.1 billion was spent throughout the research community on biomedical and other health-related research in 1974. There is a characteristic division of labor among the several sectors as performers of research and as providers or sources of funds. Both aspects are reflected in statistical profiles, in Chart 1. The performer profile on the left shows the proportion of total biomedical research funds in 1974 spent by each sector in carrying on research, and the source profile at the right shows the relative position of each sector as a source of funds. NIH is identified separately within the Federal government.

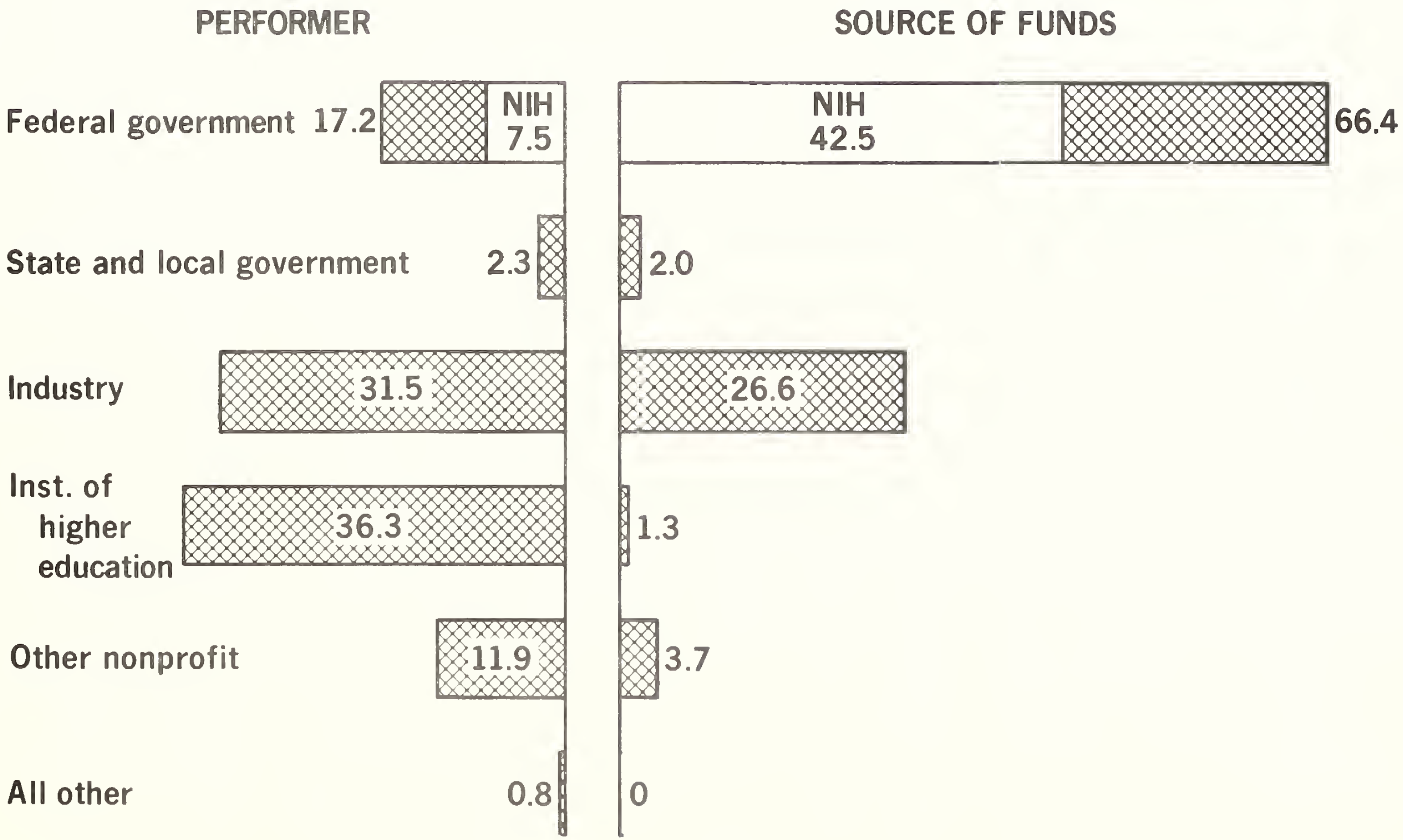
The universities (which, in the U.S., may be either independent private nonprofit institutions or units of state or local government) are the primary site for biomedical research supported by other sectors, principally Federal agencies. University-based research is predominantly fundamental in nature and is generally initiated and carried out by individual investigators and their associates in the medical schools and associated teaching hospitals and in the biology departments of the graduate schools. University biomedical research laboratories have an educational function and contribute significantly to the training of graduate bioscientists and research physicians by providing opportunities for them to work under senior investigators. As Chart 1 implies, the universities have virtually no "free" funds for their own to allocate to research.

Independent nonprofit research organizations such as research institutes and independent hospitals also provide an environment for research financed by other organizations--again primarily Federal agencies. A little less than one-eighth of total funds was spent in their laboratories. Other nonprofit organizations, such as philanthropic foundations and voluntary health agencies, are sources of special program and financial stimuli with impact well beyond that implied by

Chart 1

TOTAL U.S. FUNDS FOR BIOMEDICAL RESEARCH* 1974

By Performer and Source of Funds
Percent of Total



TOTAL R&D = $4.1 billion

*Includes other health-related research

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Source: NIH

the 3.7 percent that they contribute to total funds. For example, the health agencies (e.g., the American Cancer Society) solicit the contributions of millions of private citizens and organize programs and support research in their respective categorical areas.

Private industrial firms, primarily in the pharmaceutical; scientific, optical, and surgical instrument; and devices and appliances industries, plan and finance their own research. Their emphasis is on applied research and development leading to new or improved products for commercial sale. In addition, companies in these and other industries may carry on biomedical research and development under contract with Federal agencies. The data in Chart 1 reflect this situation--virtually all the funds for biomedical research from industrial firms (26.6 percent of the total) remained in industry in 1974 and were combined with an additional five or so percent from contracts with Federal agencies to give industry laboratories responsibility for carrying out a little more than three-tenths of the total.

The NIH and other agencies of the Executive Branch of the Federal Government, as Chart 1 indicates, were the dominant source of funds for U.S. biomedical research--together providing around two-thirds of the total. As performers, the Federal laboratories accounted for a much smaller proportion of the national total--somewhat less than a fifth.

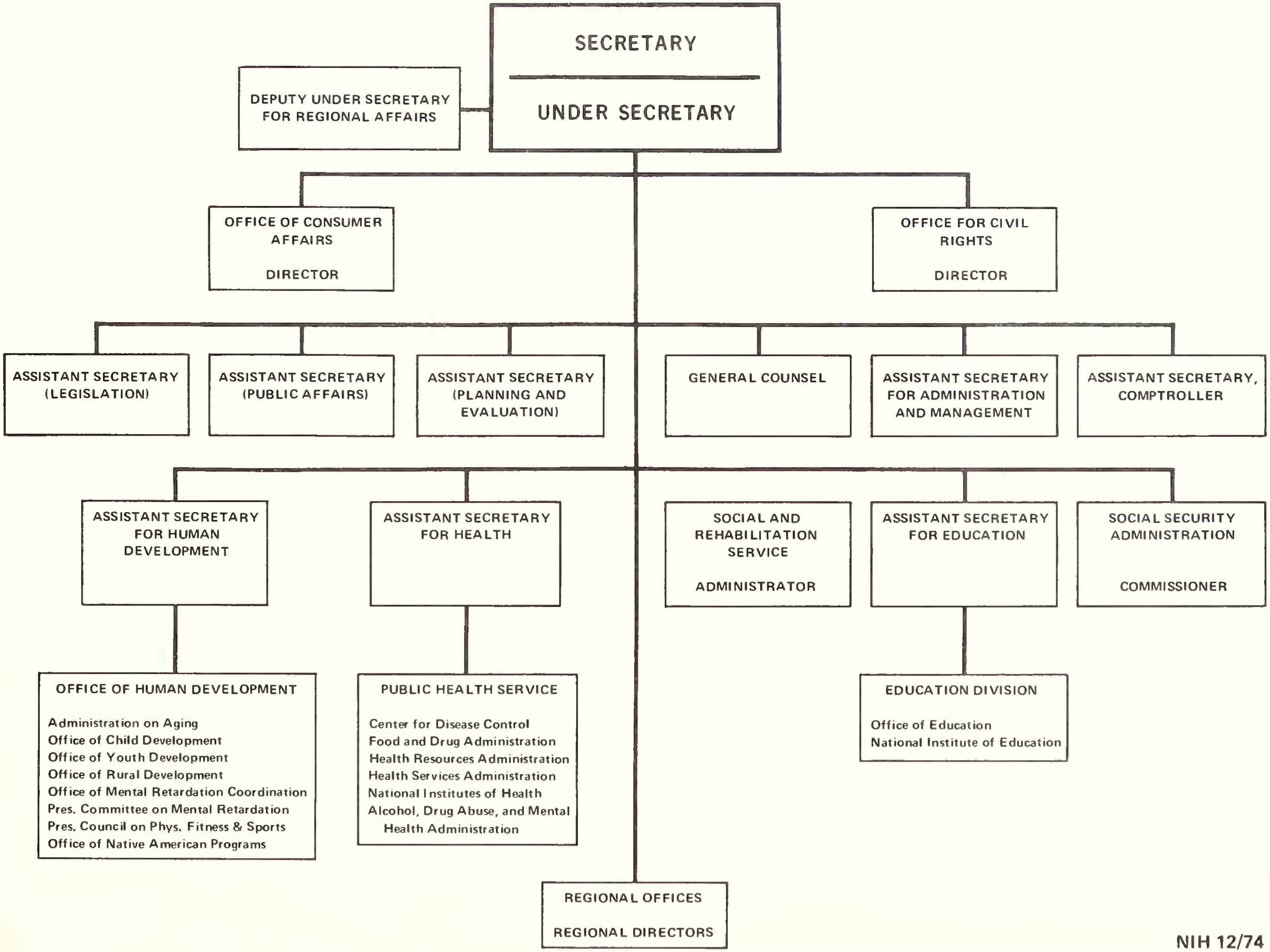
Although NIH is the major focus of Federal support of biomedical research, policy and operating responsibility in this area is widely shared by more than twenty agencies. Each has some type of authority to develop research policy related to its major objectives, to organize programs, provide the necessary administrative apparatus, distribute funds to qualified extramural investigators, and, in many instances, build and run laboratories of its own.

The Department of Defense and the Veterans Administration, for example, both support biomedical research--the one directed to achieving effective human performance in military operations and to facilitating recovery from injury and illness, the other, concerned with improving medical services and prosthetic devices for former military personnel. The Atomic Energy Commission finances research to increase knowledge of the beneficial and harmful effect of radiation on human systems. Other agencies with health research programs include the Department of Labor, the Environmental Protection Agency, the National Science Foundation, and the National Aeronautics and Space Administration.

Within the Department of Health, Education, and Welfare (Chart 2), NIH and five fellow health agencies support biomedical and other health-related research. The primary research focus of NIH and the Alcohol, Drug Abuse, and Mental Health Administration is on disease. Research financed by the other health agencies is related to their wide range of

Chart 2

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE


SECRETARY
UNDER SECRETARY
DEPUTY UNDER SECRETARY FOR REGIONAL AFFAIRS
OFFICE OF CONSUMER AFFAIRS
DIRECTOR
OFFICE FOR CIVIL RIGHTS
DIRECTOR
ASSISTANT SECRETARY (LEGISLATION)
ASSISTANT SECRETARY (PUBLIC AFFAIRS)
ASSISTANT SECRETARY (PLANNING AND EVALUATION)
GENERAL COUNSEL
ASSISTANT SECRETARY FOR ADMINISTRATION AND MANAGEMENT
ASSISTANT SECRETARY, COMPTROLLER
ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT
ASSISTANT SECRETARY FOR HEALTH
SOCIAL AND REHABILITATION SERVICE
ADMINISTRATOR
ASSISTANT SECRETARY FOR EDUCATION
SOCIAL SECURITY ADMINISTRATION
COMMISSIONER
OFFICE OF HUMAN DEVELOPMENT
Administration on Aging
Office of Child Development
Office of Youth Development
Office of Rural Development
Office of Mental Retardation Coordination
Pres. Committee on Mental Retardation
Pres. Council on Phys. Fitness & Sports
Office of Native American Programs
PUBLIC HEALTH SERVICE
Center for Disease Control
Food and Drug Administration
Health Resources Administration
Health Services Administration
National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration
EDUCATION DIVISION
Office of Education
National Institute of Education
REGIONAL OFFICES
REGIONAL DIRECTORS

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responsibilities in disease prevention, protection, product regulations, and the organization and provision of health care. The research concerns of the five other health agencies can be summarized as follows:

- Alcohol, Drug Abuse, and Mental Health Administration: research in the biological, psychological, sociological, and epidemiological aspects of alcoholism, drug abuse, and mental health and illness to support ADAMHA's leadership of the Federal effort to assure treatment, rehabilitation, and prevention services for persons with problems in these areas.

- Center for Disease Control: research, information, and public education programs in areas such as smoking and health and occupational safety and health in support of administering national programs for prevention and control of communicable and vector-borne disease and other preventable conditions, including participation in international efforts to control and prevent disease.

- Food and Drug Administration: research programs in such areas as biologics, drugs, foods, radiological health, and toxic substances to support larger responsibility for protecting national health against impure and unsafe foods, drugs, cosmetics, and other potential hazards.

- Health Resources Administration: research to support national leadership in dealing with requirements for and distribution of health resources including developing prototype health services systems, cost-effective health technology, and prototype professional standards review organizations.

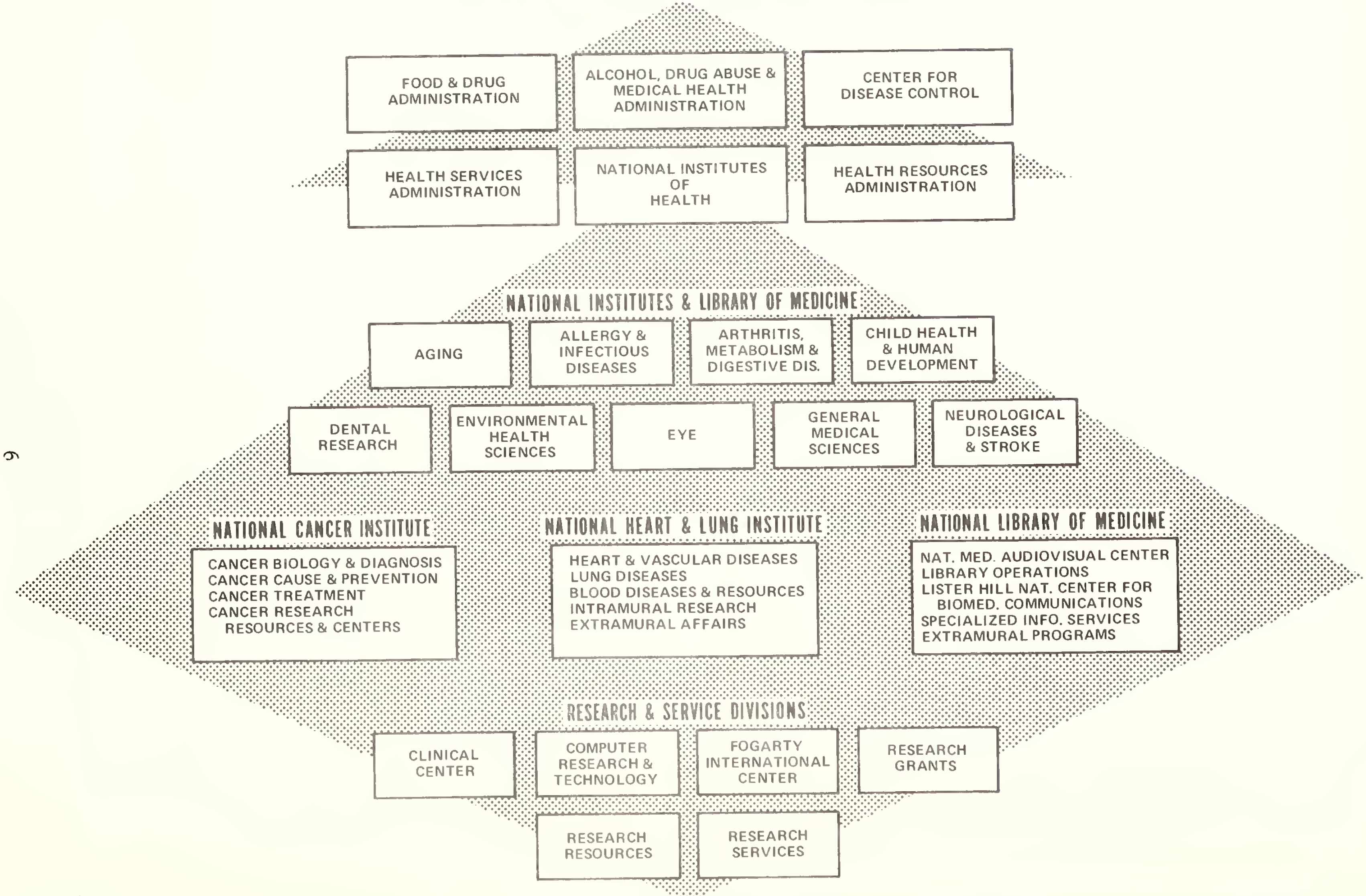
- Health Services Administration: research to support national professional leadership in the delivery of health services including improving the quality, organization, and utilization of resources in community health services, Federal health programs for special groups, maternal and child health, and family planning.

The presentation of data in Chart 1 does not do justice to the international flows into and from the U.S. biomedical research network. These include around $16 million in counterpart funds, spent under Public Law 480 by DHEW agencies, for biomedical and health-related research in the countries where the funds originated. Some $4 million of this total was for work sponsored by NIH. An additional $9 million in NIH funds went for grants and contracts abroad; slightly more than half of this sum was from the National Cancer Institute.

Organization of NIH. As Chart 2 indicates, NIH is located in the Department of Health Education and Welfare (DHEW). The Department is headed by a Secretary who is a member of the President's Cabinet.

Chart 3

DHEW
ASSISTANT SECRETARY FOR HEALTH


FOOD & DRUG ADMINISTRATION
ALCOHOL, DRUG ABUSE & MEDICAL HEALTH ADMINISTRATION
CENTER FOR DISEASE CONTROL
HEALTH SERVICES ADMINISTRATION
NATIONAL INSTITUTES OF HEALTH
HEALTH RESOURCES ADMINISTRATION
NATIONAL INSTITUTES & LIBRARY OF MEDICINE
AGING
ALLERGY & INFECTIOUS DISEASES
ARTHRITIS, METABOLISM & DIGESTIVE DIS.
CHILD HEALTH & HUMAN DEVELOPMENT
DENTAL RESEARCH
ENVIRONMENTAL HEALTH SCIENCES
EYE
GENERAL MEDICAL SCIENCES
NEUROLOGICAL DISEASES & STROKE
NATIONAL CANCER INSTITUTE
CANCER BIOLOGY & DIAGNOSIS
CANCER CAUSE & PREVENTION
CANCER TREATMENT
CANCER RESEARCH RESOURCES & CENTERS
NATIONAL HEART & LUNG INSTITUTE
HEART & VASCULAR DISEASES
LUNG DISEASES
BLOOD DISEASES & RESOURCES
INTRAMURAL RESEARCH
EXTRAMURAL AFFAIRS
NATIONAL LIBRARY OF MEDICINE
NAT. MED. AUDIOVISUAL CENTER
LIBRARY OPERATIONS
LISTER HILL NAT. CENTER FOR BIOMED. COMMUNICATIONS
SPECIALIZED INFO. SERVICES
EXTRAMURAL PROGRAMS
RESEARCH & SERVICE DIVISIONS
CLINICAL CENTER
COMPUTER RESEARCH & TECHNOLOGY
FOGARTY INTERNATIONAL CENTER
RESEARCH GRANTS
RESEARCH RESOURCES
RESEARCH SERVICES

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NIH is one of the six health agencies in the Public Health Service (herein called Health) under the Assistant Secretary for Health, a line official.

NIH is a composite agency made up of eleven categorical institutes, the National Library of Medicine, and six research and service divisions, each with its own director and staff. The agency as a whole is headed by the Director, NIH (Chart 3). The categorical organization of the institutes is a result of pressures from many points in the biomedical research network--particularly of decisions by the Legislative and Executive Branches of the Government--that have shaped the health research strategy. The names of 10 of the 11 national institutes, all established by the Congress, reflect concentration on a single disease, related sets of diseases, organs and systems, health problems, or stages of life. The eleventh institute, the National Institute of General Medical Sciences, is responsible for areas of bioscience that cannot be fully encompassed within a disease-oriented organization. The National Library of Medicine, the Nation's chief medical information resource, is responsible for providing medical library services and for developing and managing a range of bibliographic and biomedical communications capabilities to serve all sectors of the biomedical community.

Of the six NIH divisions, three have their own operating programs. The Clinical Center is a research hospital which houses the intramural clinical research programs of the individual institutes. The John E. Fogarty International Center for Advanced Study in the Health Sciences supports an international program of advanced study and training and administers the Gorgas Memorial Laboratory in Panama. The Division of Research Resources supports clinical research centers, animal resources programs, computer centers and other special programs in support of health-related research. The other divisions provide various support services, on an NIH-wide basis, for intramural and extramural research operations.

Some general concepts

No formal statement exists of the principles followed by NIH in formulating and implementing national biomedical research policy. It would be surprising if there were such a text, in view of the dynamism of the biomedical research network and the continuing evolution of the Federal role and policies in the larger health area. Both these forces continually stimulate the national health effort to provide better care for Americans. But they imply somewhat different emphases. The biomedical research activity generates action to optimize the output of knowledge from promising work in basic science. The larger Federal health role raises the question of how to optimize the contribution of research to meeting the Nation's health needs. Yet, for present purposes, some general statements of the concepts that have guided the NIH can be made, as follows:

1. The mission of the NIH as a Federal health research agency is to advance the U.S. capability for raising the level of health through finding ways of improving the diagnosis, treatment, cure, and prevention of disease.

2. This can be done by:

   - supporting fundamental research to enlarge our understanding of the underlying biology of health and disease; and

   - developing and conducting organized research activities aimed at specific disease or problem areas, where the scientific opportunities for a major advance seem clear and where circumstances and societal urgencies warrant an organized centrally managed effort.

3. The most effective means by which a central body like NIH can broaden and exploit biomedical knowledge is by:

   a. drawing on the best technical advice and evaluation available regarding the quality of proposed projects, the state of the art, and significant opportunities and problems;

   b. stimulating those individuals with the most creative scientific minds and the most productive new ideas to do their best work by providing working arrangements and conditions that favor productivity, including training opportunities, facilities, and advanced equipment, where appropriate; and

   c. providing resources for directing new knowledge back into the research network and for making it widely available to the health services community.

Institutional arrangements and relationships

The major institutional arrangements and relationships important in policy formulation and implementation at NIH can be described under the following headings:

1. the internal working relationships between the Office of the Director and the institutes in policy and program formulation;

2. the public advisory system that provides specialized scientific and lay judgments at all levels of NIH--external advisers who make a critical contribution to internal operating decisions;

3. external relationships with higher levels of the Executive Branch and the Congress, the NIH "constituencies," and independent *ad hoc* commissions of inquiry;

4. approaches for maximizing high quality research output through support of intramural and extramural research; and

5. approaches to conveying the results of biomedical research to researchers in a position to develop them further, to medical centers, to practicing physicians, and to the general public.

Working relationships between the Office of the Director, NIH, and the Institutes

There is a division of policy making and policy implementation responsibilities between the central Office of the Director, National Institutes of Health, and the component institutes. The latter, with authority within their respective areas of categorical responsibility, plan and carry out the operating programs of the NIH. The Office of the Director has a twofold function. It represents the corporate NIH identity in dealing with the outside world, including the rest of the Department. And, with authority spanning all the institutes, it provides internal coordinating policy direction to achieve maximum overall effectiveness.

Interaction between the level of the institute and that of the Office of the Director takes place in an ambiance of widely shared common knowledge of the mission of NIH as a whole and the objectives, problems, and capabilities of the several institutes; of general familiarity with policy orders and guidance from the Congress and from higher levels in the Executive Branch; and of broad understanding of trends in technical advice and evaluation from the scientific community.

Office of the Director, NIH. The Director, NIH, is assisted by a Deputy Director with general responsibilities and a Deputy Director for Science. Six Associate Directors and an Assistant Director serve in the special areas indicated on Chart 4 and act as principal advisors to the Director and the Deputies.

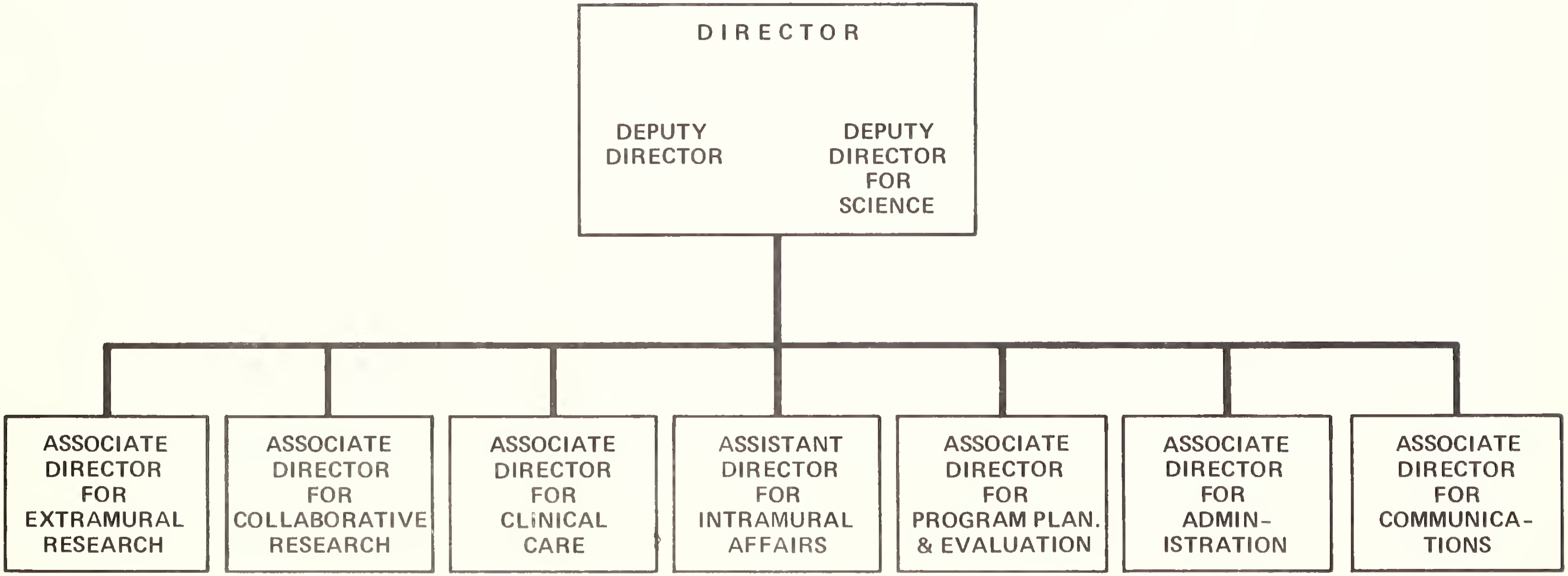
The Director and his associates, usually referred to as "OD staff" or "OD/NIH," are responsible for decision-making on emerging NIH-wide policy issues, for setting NIH-wide goals, for planning the allocation of resources between the institutes, for reviewing existing institute programs and participating in the planning of new ones, and for generally assuring the accountability of the agency for the objectives and resources allocated to it.

The key means by which overall program coordination and resource allocation by OD/NIH customarily take place is through the annual budget process and review of the longer range plans of the institutes. Certain assessments involving the disposition of resources are uniquely within OD/NIH competence because they require a trans-NIH view of program balance and priorities. Typically, these deal with relating total funds requested to total funds available, where a judgment must often be made on whether a given program should be instituted or

U.S. Department of Health, Education, and Welfare
Assistant Secretary for Health

Chart 4

OFFICE OF THE DIRECTOR
NATIONAL INSTITUTES OF HEALTH


DIRECTOR
DEPUTY DIRECTOR
DEPUTY DIRECTOR FOR SCIENCE
ASSOCIATE DIRECTOR FOR EXTRAMURAL RESEARCH
ASSOCIATE DIRECTOR FOR COLLABORATIVE RESEARCH
ASSOCIATE DIRECTOR FOR CLINICAL CARE
ASSISTANT DIRECTOR FOR INTRAMURAL AFFAIRS
ASSOCIATE DIRECTOR FOR PROGRAM PLAN. & EVALUATION
ASSOCIATE DIRECTOR FOR ADMINISTRATION
ASSOCIATE DIRECTOR FOR COMMUNICATIONS

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expanded. Other uniquely OD/NIH judgments, made in the forward planning process, include identification of points where:

- two or more institute programs compete for the same research resources or require coordination because of overlapping interest,
- there are areas of research need or opportunity to which no institute programs are currently addressed, or
- some central management or support mechanism is needed.

A number of factors limit the freedom and scope of these OD/NIH decisions:

- Initiatives for new programs often come from forces outside the agency and lead to assignments that are not necessarily in the form that NIH would have chosen. The assignments may preempt resources that would have been used in other ways.
- In any given year, a large percent of any institute's resources is already committed by previous commitments, leaving a relatively small margin of discretionary funds.
- In a time of tight budgets, such as the present, there are further constraints: the trend in funds requested by the President and appropriated by the Congress to most institutes--with the exception of the Cancer and Heart/Lung Institutes--is more or less level; personnel ceilings and construction deferrals or limitations set by the Administration act to inhibit program expansion.

The institutes. In addition to a director, top institute staffing usually includes associate directors, each with purview over a major sector of activity: extramural research, intramural research, program planning, and administration.

The pattern of management at NIH is highly participatory. Central policy guidance by OD/NIH is complemented by considerable decentralization of operating responsibility and authority to the institute directors and their associates. Authority for defining boundaries and content of scientific programs, within the broad limits set by statute, and for development, implementation and administrative support of programs rests with the director of each institute who may use a variety of methods to carry out these functions. Each institute is responsible--within budget constraints--for the full range of research activity that it deems relevant to its categorical disease interests--from fundamental to clinical, both intramural and extramural; for communicating its objectives and plans for support programs to interested scientists in academic and other institutions; for identifying the special manpower needed for its research; for proposing means of assuring a supply of the required manpower when needed; and for handling relationships with its various scientific, professional, and health constituencies.

Institute staff make decisions on the content, priorities, and allocation of money and staff to particular programs on the basis of their familiarity with the outcomes of past research and the ideas for modified or new programs that are constantly flowing in from investigators and expert advisors. Decisions coalesce into preliminary recommendations during the process of budget development. At that time, funding levels are proposed for programs, debated, and negotiated on the basis of judgments on subprograms or individual projects within a specific program and as between competing programs. Progress made as a result of past expenditures--accomplishments realized and opportunities opened--influences staff in proposing new budget levels.

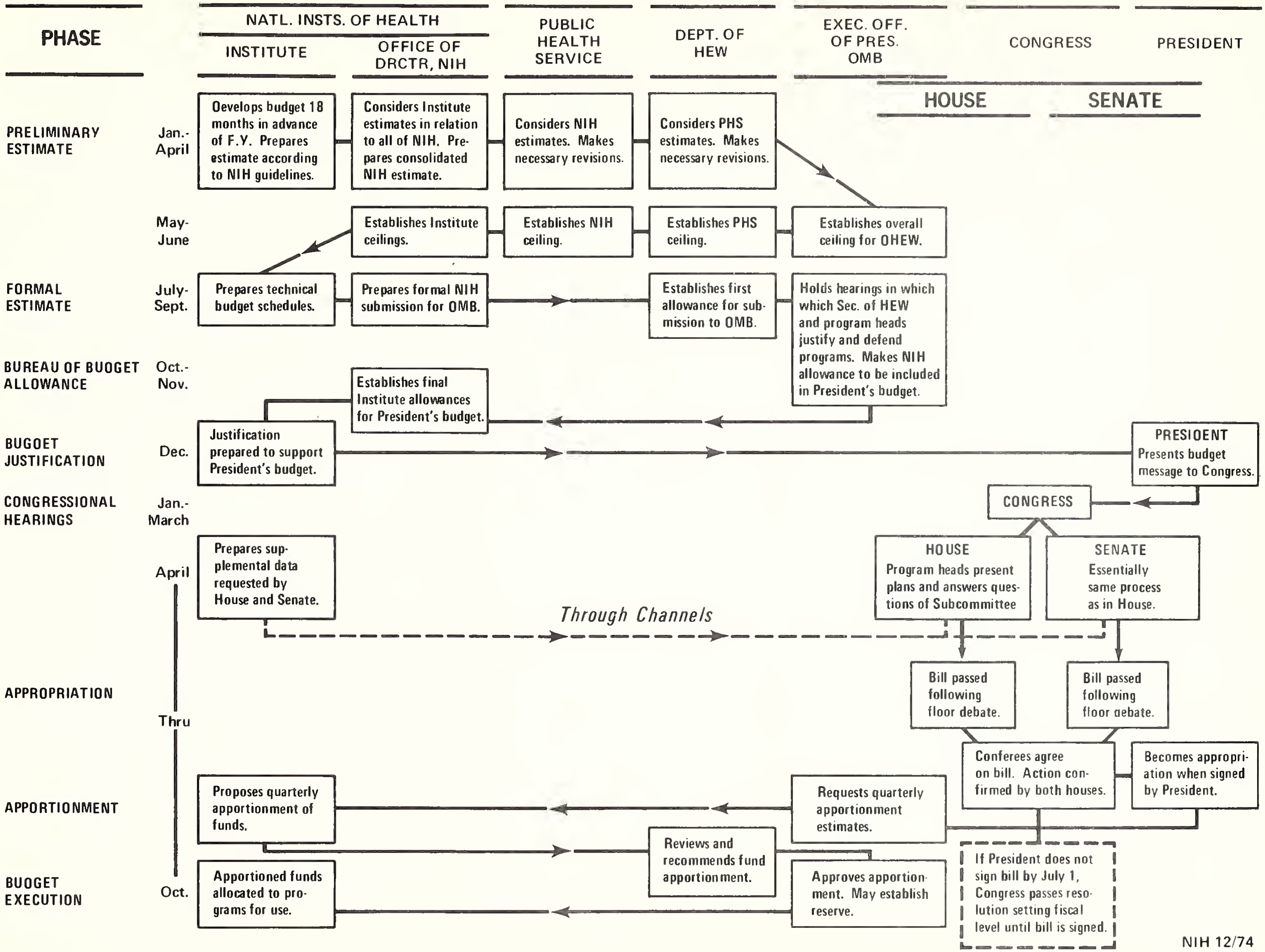
Proposed institute budgets covering all programs are worked out in the office of the institute director on the basis of institute-wide criteria and some necessary give and take among programs. They are then transmitted up the line to the OD/NIH for NIH-wide review and negotiation and, finally, incorporation into the proposed NIH budget. This is then considered and modified by the Office of the Assistant Secretary for Health, together with the proposals of the other Health agencies, in working up the Health budget. Throughout, negotiations and decisions take on more general policy import as the process of budget development, review, approval, and execution, moves from the individual institutes up the line to the Assistant Secretary for Health, to the President, and the Congress. At the same time, because of the technical nature of programs, Institute directors are often invited to discuss their programs directly with representatives of the Office of Management and Budget and, in addition to the Director, NIH, to testify on behalf of their proposed budgets at Congressional Appropriations Committee hearings.

The budget process is so universal that there is no need to detail it further here. For background information, the entire NIH budget cycle is summarized in Chart 5. (Recent legislation for the National Cancer Program is unique in that it provides that the proposed budget for the National Cancer Institute shall be transmitted directly to the President, without modification by the Director, NIH, or the Secretary, HEW.)

Initiatives for new or significantly revised programs can come from within or outside the institute concerned. Regardless of source, the basic ground work for implementing the initiative is carried out by that institute, with varying degrees of OD/NIH participation and with OD review and approval. In some cases, such as the recent legislation ordering the establishment of a separate Institute on Aging and transferring to it the responsibility for research on aging previously under the National Institute of Child Health and Human Development, NIH has coordinated an interagency implementation effort including other

Chart 5

NATIONAL INSTITUTES OF HEALTH - BUDGET PROCESS


PHASE
NATL. INSTS. OF HEALTH
INSTITUTE
OFFICE OF DRCTR, NIH
PUBLIC HEALTH SERVICE
DEPT. OF HEW
EXEC. OFF. OF PRES. OMB
CONGRESS
HOUSE
SENATE
PRESIDENT
PRELIMINARY ESTIMATE
Jan.-April
Develops budget 18 months in advance of F.Y. Prepares estimate according to NIH guidelines.
Considers Institute estimates in relation to all of NIH. Prepares consolidated NIH estimate.
Considers NIH estimates. Makes necessary revisions.
Considers PHS estimates. Makes necessary revisions.
May-June
Establishes Institute ceilings.
Establishes NIH ceiling.
Establishes PHS ceiling.
Establishes overall ceiling for DHEW.
FORMAL ESTIMATE
July-Sept.
Prepares technical budget schedules.
Prepares formal NIH submission for OMB.
Establishes first allowance for submission to OMB.
Holds hearings in which which Sec. of HEW and program heads justify and defend programs. Makes NIH allowance to be included in President's budget.
BUREAU OF BUDGET ALLOWANCE
Oct.-Nov.
Establishes final Institute allowances for President's budget.
BUDGET JUSTIFICATION
Dec.
Justification prepared to support President's budget.
PRESIDENT Presents budget message to Congress.
CONGRESSIONAL HEARINGS
Jan.-March
CONGRESS
HOUSE Program heads present plans and answers questions of Subcommittee
SENATE Essentially same process as in House.
April
Prepares supplemental data requested by House and Senate.
Through Channels
APPROPRIATION
Thru
Bill passed following floor debate.
Bill passed following floor debate.
Conferees agree on bill. Action confirmed by both houses.
Becomes appropriation when signed by President.
APPORTIONMENT
Proposes quarterly apportionment of funds.
Requests quarterly apportionment estimates.
Reviews and recommends fund apportionment.
If President does not sign bill by July 1, Congress passes resolution setting fiscal level until bill is signed.
BUDGET EXECUTION
Oct.
Apportioned funds allocated to programs for use.
Approves apportionment. May establish reserve.

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agencies, both in and out of DHEW, with an interest in research on aging.

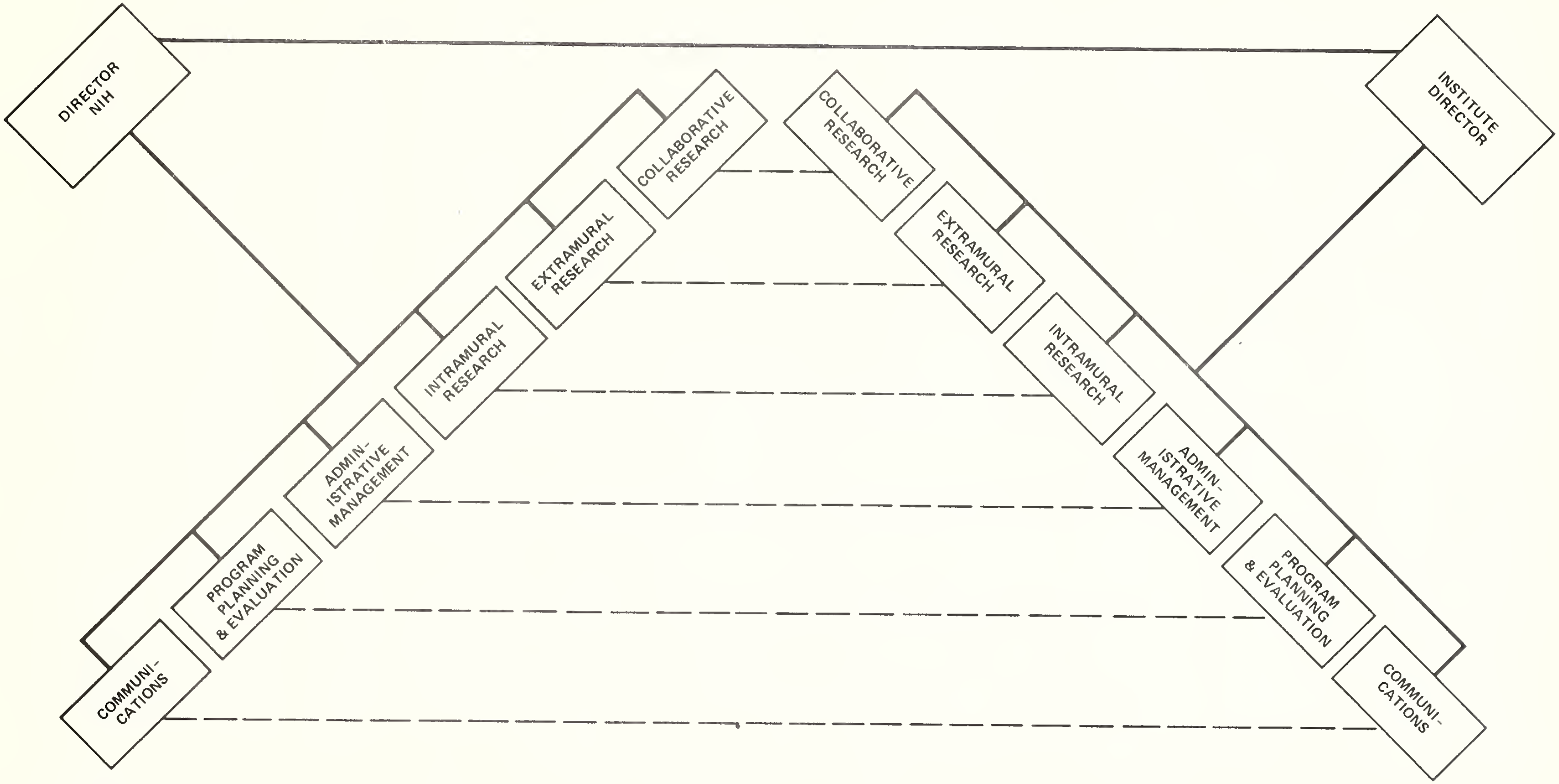
Longer range planning as a policy tool takes many forms at NIH. Increasingly, the Congress is insisting that the institutes draw up national plans as frameworks for decisions on new programs oriented to specific diseases or problems. The large-scale, detailed plan of the National Cancer Institute and the similar plan of the National Heart and Lung Institute are widely known examples of such explicit planning. Historically, all the institutes have planned but no two have followed the same course. Differences in the course of institutional development and objectives, in the state of the art of disciplines supported, and in the philosophy of institute staffs and their advisory bodies have combined to produce a range of approaches. From the point of view of management policy, the variety of planning approaches may be considered a source of desirable diversity and a stimulus to innovation or it may be taken as evidence of a lack of central direction. This is a problem that occurs throughout organized research and is not unique to biomedicine.

Formal OD/NIH--institute relationships. Day-to-day discussion and decision-making by institute and OD/NIH staff working together is complemented by formal consultation between the two levels on both a line and staff basis. Acting on the central line or chain-of-command relationship, the Director, NIH, chairs a weekly meeting with institute directors, as a group, to explore common problems, identify policy issues, and work out positions. Institute directors also report formally to the Director, NIH, on long range plans, proposed budget, compliance with DHEW regulations governing research support, and a host of other matters involving accountability or conformance with Federal policies. The Director then reports, where required, to the Assistant Secretary for Health.

At the same time, on a functional or staff-to-staff basis, the institute scientific directors (who are responsible for the research programs carried on within the institutes themselves) meet with the Deputy Director for Science, NIH; the institute clinical directors meet regularly with the Associate Director for Clinical Care; and the institute officers in charge of extramural programs meet, as the Executive Committee on Extramural Affairs (ECEA), with the Associate Director for Extramural Research and Training, NIH. Since grants and contracts for extramural research, development, training, and construction account for around 85 percent of the NIH budget and support the work of tens of thousands of scientists in hundreds of institutions, the work of the ECEA is critical. The Associate Director for Collaborative Research meets with institute collaborative program directors and other parallel joint staff meetings take place in the areas of public information, program planning and evaluation, and the components of administration.

Chart 6

"MATRIX" ASPECT OF THE RELATIONSHIP
BETWEEN THE OFFICE OF DIRECTOR, NIH, AND THE INSTITUTES



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"Matrix management" results when this functional relationship between staff officers at different levels is combined with the conventional chain-of-command within institutes and between institute directors and the Director, NIH. The combination makes it possible for institute directors to exercise operating responsibility for their own programs and for the Director, NIH, to retain the line functions of oversight, control, and policy formulation, while staff of the Office of the Director are able to play a significant role in decision-making in the scientific and management areas within institutes. Chart 6 attempts to depict the matrix elements in the relationship between OD/NIH and the institutes.

NIH is only one of many large complicated organizations that are tending toward this mixed mode of management. The trend has been rather vividly described by Harlan Cleveland, President of the University of Hawaii, in the following words:

> The extraordinary growth in the number and public importance of decisions to be made will require new kinds of organizations, managed in new ways by new people. The organizations that get things done will no longer be hierarchical pyramids with most of the real control at the top. They will be systems--interlaced webs of tension in which control is loose, power is diffused, and centers of decision are plural.*

The public advisory system. The cornerstone of the advisory system at NIH and perhaps one of the agency's major contributions to the management of large Federally supported science programs is the dual review process. This process is designed to keep a clear separation between: (a) decisions on the scientific merit of a proposed project, and (b) decisions on relevance to institute program and relative importance from the point of view of availability of institute funds. This separation is achieved by assigning the decisions to two different sets of advisory committees.

- Scientific merit is judged by specialized initial review groups (IRG's) or study sections in the Division of Research Grants (DRG) which review all new research proposals for all the institutes. The subject scope of an IRG may be a medical specialty, a biomedical discipline, or a focus of interest (such as population). Its members are outside scientists who are the peers of those submitting proposals, by virtue of their knowledge and expertise in the group's area.

- Program relevance is judged by the advisory council to the director of the institute which will fund the project. Councils are composed of knowledgeable laymen and scientists with recognized competence in the disease area of institute concern. By statute, no award can be made by NIH unless it is recommended by a council.

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* Harlan Cleveland, "The Decision Makers," The Center Magazine, September/October, 1973, p. 11.

(Decisions on the relevance and specific assignment of incoming proposals to particular IRG's and institutes are made by a central staff in the Division of Research Grants.)

The IRG decision on scientific merit is made first and proposals recommended for approval are each given a recommended priority rating to guide the cognizant advisory council and institute director. Next, the council, assisted by institute staff, assesses the relevance of the proposal to the institute's program. It recommends to the director an "order of payment" or priority for proposals which it considers highly relevant, within the limits of institute funds available. (This limit is tight--no institute in recent years has had sufficient funds to support more than half the projects approved by an IRG.)

In setting payment order, an institute council generally gives considerable weight to the scientific priority evaluation of the IRG. There are, however, times when a council considers a proposal that has only marginal priority approval so relevant to a particular institute program that it recommends support regardless of the higher ratings given to other projects. In effect, council revision of IRG scientific priorities in the light of program relevance increases the probability that proposals that are funded will meet institute program goals.

Following council approval and recommendations on payment order, the actual decision on priority of award and on the level of funds to be awarded is made by the institute director acting for the Director, NIH.

Both the IRG's and advisory councils have functions in addition to dual review. The IRG's provide the institutes with occasional assessments of the state of the art in their subject area and of emerging opportunities. The institute advisory councils meet regularly to advise institute directors on a broad range of issues.

The NIH advisory system includes several other components. These are:

- The Advisory Committee to the Director, NIH, composed of distinguished laymen and scientists, science administrators, and biomedical scientists.

- The Board of Scientific Counselors of each institute, consisting of outside leaders in the basic and clinical sciences within the institute's purview. It advises on the program policy of institute intramural research, particularly from a long-range point of view.

- Program advisory committees that meet the need of program staff for advice on such matters as criteria for program development or the drafting of protocols for new types of work. These committees are composed of leading outside authorities in basic and clinical sciences related to the subject focus of their programs.

External relationships with other sources of direction and advice

As lead agency in biomedical research, NIH shares responsibility with other forces that either have formal, including Constitutional, cognizance over Federal health activities or that have semi-formal or informal but, nonetheless, significant power.

Higher levels of the Department and Office of the President. Three higher Executive Branch levels have authority over NIH--the Office of the Assistant Secretary for Health; the Office of the Secretary of Health, Education, and Welfare; and the Executive Office of the President, within which both the Domestic Policy Council and the Office of Management and Budget carry out their responsibilities. In addition, the Director of the National Science Foundation, in his capacity as the Science Adviser named by the President, may be consulted, or may profer advice on the program and activities of NIH, as well as of all other Federal civilian science agencies.

The terms and constraints of NIH-Health-Departmental relationships in the formulation of biomedical research policy are set by NIH's position (a) as one of several health agencies in the Public Health Service, headed by an Assistant Secretary, with line responsibility for all these agencies, (b) within a Department equipped with strong department-wide units for planning and evaluation and financial management (Chart 2).

The Director, NIH, in his role as corporate head of NIH, moves upward from NIH to the Health level to justify and negotiate out the general content and the dimensions of the proposed NIH budget. This budget then becomes part of the Health budget--although retaining a separate identity--and the whole is then readied for presentation by the Assistant Secretary for Health to the Office of the Secretary, HEW. In this process and in many other policy matters, the Assistant Secretary for Health may speak for the NIH in the Department-wide context and outside. On the other hand, there are important situations, such as the creation of a new institute or major program, or the drafting and promulgation of regulations on the conditions governing the use of NIH research funds, which require close collaboration between cognizant staff from several levels--the institute, OD/NIH, the Office of the Assistant Secretary for Health, and a Department-wide office.

The Director, NIH, with his fellow health agency heads and the staff of the Assistant Secretary for Health, meet frequently as the Health Policy Board and participate in planning the ways in which to carry out the diverse health responsibilities assigned them under

DHEW organization. Because the major national health care programs for the elderly and the medically indigent are administered by DHEW agencies outside the Public Health Service, NIH is the largest (in terms of funding) of the agencies under the Assistant Secretary. Questions concerning the bounds and relationships between NIH activities and the health care, preventive, and regulatory activities of the other Health agencies are inevitable. A brief exploration can illustrate the nature of the issues raised.

The question could be asked, for example, on how the control programs of the Cancer and Heart/Lung Institutes differ from those of other Public Health Service agencies for which disease control is a major responsibility--that is, the Center for Disease Control and the Alcohol, Drug Abuse, and Mental Health Administration. Here, a point to bear in mind is that these NIH programs were not organized to provide routine medical care. They were mandated by Congress as part of the research programs of the two institutes and are, therefore, being managed as demonstration programs to convey information on the applications of the latest clinical findings as quickly as possible to practicing physicians. Experience with them and with those programs managed by other Public Health agencies will gradually make it possible to define more precisely different types of control programs and their relationship to various Federal health objectives.

Similarly, a question could be posed concerning clinical trials. The statistically designed clinical trial is a widely used tool for testing and evaluating the hypotheses and tentative findings on the efficacy of modes of treatment that emerge from NIH research. Food and Drug Administration acceptance of the safety and efficacy of a drug which a drug company wishes to market also requires clinical trials; and sometime in the near future clinical trials may be needed for decisions on accepting new medical practices for reimbursement under national health insurance. Here the question might be raised as to why NIH, with its expertise in clinical trials, could not carry out such trials for other Health agencies. From the NIH point of view, clinical trials are part of the development phase of biomedical research and development and are linked to the evaluation of research results and decisions on the future course of particular programs. If NIH were required to shift attention to routine clinical trials for regulatory or health insurance purposes, this would introduce critical competition for resources.

There are no well defined NIH positions on either of these matters. Both are currently under study.

Formal NIH contacts with the President's Office of Management and Budget are at budget hearings at which OD/NIH staff and top institute staff "back up" other Health and Department officers in justifying the proposed budget. Informal OMB-NIH meetings--held at the instance of either party--deal with various issues of NIH policy and management.

Presidential messages and statements on Federal health policy in general or on specific legislation are also sources of direction.

Congress, NIH constituencies, ad hoc groups: a national forum. The open interaction between the Congress, the Executive, a range of health research-oriented constituencies, special *ad hoc* advisory groups, and the press has, in effect, created a national public forum on issues of Federal support of biomedical research. NIH, together with the Office of the Assistant Secretary for Health and Department-wide staff are responsible--within their respective spheres--for participating in, responding to, and sometimes initiating events in this forum and for interpreting and implementing orders and directives that emerge from it.

Over 40 *Congressional committees* and subcommittees have some type of cognizance over aspects of Federal health policy and may hold hearings, establish a printed record, and propose legislation on matters affecting the work of NIH. In particular, two committees in the Senate and two in the House of Representatives have critical direct power over the shape of NIH programs and level of resources. One set of these committees has substantive oversight authority. It reviews and recommends program activities and proposes an authorized or maximum level of expenditures for various categories of NIH work. The other set consists of the appropriations subcommittees that propose bills appropriating funds for the agency's activities--within the limits set by authorizations.

The necessity of appearing before Congressional committees and OMB staff to present and justify NIH programs and budgets also affords the Director, his immediate associates, and institute directors an opportunity to negotiate and exchange views with these two important sources of guidance.

The legislative and executive direction to NIH on a particular issue may not always coincide and may require further elucidation within the Department. Nonetheless, orders from these branches of the Federal establishment embody the political resolution of popular demands for Federal action on health that derive from humanitarian and social as well as scientific forces.

The *professional, health, and academic constituencies* of NIH are also sources of policy advice, program proposals, and criticism. They are active in presenting their points of view to the Congress, the press, and directly to the public and are often represented on *ad hoc* commissions of inquiry on NIH problems. Associations representing physicians, nurses, and other medical and paramedical personnel make themselves heard. The health constituencies include over 50 disease-oriented voluntary health organizations such as the American Heart Association and the National Foundation and hospital organizations such as the American Hospital Association. The academic constituency of medical schools and the biology departments of graduate schools often expresses its concern through statements by the Association of American Medical Colleges and the Federation of Societies of Experimental Biology. Distinguished bioscientists are often well known to Congressmen and their staff and may be invited as individuals to testify on issues concerning NIH.

Independent ad hoc advisory groups appointed by and reporting back to the President, the Secretary, HEW, or the Congress have been significant sources of guidance on program substance or management. Depending on the issues studied, these groups have been composed of lay or scientific persons or a combination of both. An outstanding example of such a group was the NIH Study Committee (the "Wooldridge Committee") which functioned during 1964-65. Its panels were made up of persons experienced in public and private biomedical research management who studied all aspects of NIH administration. The Committee reported to the President with extensive recommendations for improving central planning and policy making and the management of extramural and intramural programs at NIH. Major changes in NIH modes of work were made as a result of the report.

Currently, a new distinguished ad hoc group, the President's Biomedical Research Panel, is being organized at legislative direction. Its assigned scope encompasses the entire biomedical research program of the NIH (and the behavioral research program of the National Institute of Mental Health, a component of the Alcohol, Drug Abuse, and Mental Health Administration). With respect to the NIH program, the Panel is instructed to:

- carry out a review and assessment
- identify and make recommendations on policy issues concerning subject and content
- identify and make recommendations on issues related to organization and operation.

The National Academy of Sciences/National Research Council, a non-governmental body chartered by the Congress, has provided continuing assistance in the area of ad hoc advice through its capability for organizing and managing special groups to deal with issues of science policy, as requested by the Congress, or by the Executive Branch. Recently, a committee under the Academy's Institute of Medicine reported on the cost of medical education. A new committee is now being organized, at Congressional directive, by the Research Council's Commission on Human Resources, to provide guidance for NIH planning of training programs by furnishing annual estimates of the need for various categories of biomedical research personnel.

A striking outcome of the operation of the informal national forum on biomedical research policy, created by the open debate on this subject among representatives of the groups that have just been described, has been an increase in the variety of forces which can bring new NIH programs into being. Six brief references to the results of somewhat different special program initiatives are illustrative.*

- National Cancer Program--traceable to a combination of Congressional and Presidential initiatives (stimulated by special cancer constituencies including the American Cancer Society) and backed by strong public interest.
- Sickle Cell Disease Program--a Presidential initiative, but obviously of special concern to the black community.
- National Hypertension Program--a response to direct personal leadership of the DHEW Secretary.
- National Dental Caries Program--originated within the scientific program of an institute.
- Artificial Kidney Program--a direct Congressional initiative, reacting to testimony by citizen witnesses.
- Cholera Research Program--launched within the National Institute of Allergy and Infectious Diseases with international sponsorship.

Approaches to support of research

Intramural research activities. All but one of the institutes carry on intramural laboratory and clinical research programs within NIH under the general direction of the institute Scientific Directors. These consist of laboratory programs in basic research related to the institute's mission and of clinical studies of patients with diseases of direct interest, carried out primarily in the Clinical Center at the NIH Bethesda campus.

Intramural program development is influenced by several factors:

- the expertise of the intramural scientific staff and their ideas for new or modified programs--as influenced by an internal peer review process,
- the advice of the institute Advisory Board of Scientific Counselors,
- insights gained in contacts between intramural staff and scientists working at other institutions, and

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* Report of the NIH Program Mechanisms Committee, February 14, 1973, p. 25.

- issues raised and decisions reached at meetings of institute Scientific Directors with the Deputy Director for Science, NIH, and at meetings of the institute Clinical Directors with the Associate Director for Clinical Care, NIH.

Intramural programs are relatively small compared to the NIH extramural effort but they make distinctive contribution to overall research policy formulation and implementation in a number of ways:

- They provide a science base that strengthens extramural support activities.
- Their breadth provides more possibilities for short-range, informal exchange of ideas between scientists than can occur in most other biomedical research laboratories.
- They provide an environment uniquely concentrated on research with no requirement of additional orientation to teaching or health services. In effect, they are prototype medical research laboratories and clinical research facilities.
- They offer opportunities for interaction and collaboration between scientists from different fields and disciplines and exceptional opportunities for those, including younger scientists, who wish to upgrade or expand their scientific skills.
- The relative financial and organizational stability of intramural research permits activities which can be undertaken only with great difficulty or not at all by outside institutions.

Research carried on extramurally. Traditionally, the bulk of research supported by NIH has been carried on extramurally, primarily with the support of grants and, to a lesser extent, under contract. Grants have been used for research support when it appeared that results of interest to NIH were most likely to emerge if the individual investigators retained considerable freedom to follow their own approach. Contracts have been the instrument when NIH has been able to clearly specify the desired product, service, or outcome. In recent years, grants have been expanded to cover much larger projects than the relatively small classic investigator-initiated project within a particular discipline, and contracts have increased in number, size, and complexity of objective.

Expansion in the size of grants has been stimulated by the fact that fundamental research supported by individual investigators in particular areas has gradually created a body of basic knowledge and understanding that opens up new types of opportunity. Some of these appear to require collaborative multidisciplinary exploration on a large scale, often using complex facilities, through specially organized units or comprehensive programs. Two new types of grant to academic institutions have been developed to care for this need--the center project grant, supporting a special inter-departmental unit and integrated research program, and the program project grant supporting one or more projects that are part of a larger long-term multidisciplinary effort with a central unifying research objective.

The increase in number and size of contract-supported research programs has stemmed from the conviction in Congress, the Administration, the health research constituency, and among NIH staff that more systematic planning with sharply defined targets should be used for reaching results in areas where the state of the art gives some basis for hope that tangible benefits will flow from this directed approach. As a result, large-scale centrally managed programs of directed research relying heavily on contracts with universities, research institutes, commercial laboratories, and other government agencies have been organized by both the Cancer and Heart and Lung Institutes. As appropriate, other institutes also administer comparably focused but smaller-scale centrally managed research programs.

The growth of large-scale research programs has been accompanied by continuing discussion of such policy issues as the following:

- How can the essential elements of peer review be brought into the evaluation of outside proposals for large-scale, many-sided grants and the evaluation of NIH staff plans for large contracts, to assure that research quality is safeguarded?

- Has the trend toward large-scale grants resulted in too large a proportion of funds being committed to these kinds of activities? Is there a topping out or optimum point in the relationship between smaller and larger scale grants in any particular program?

- What responsibility, if any, does NIH have for the impact on medical schools and other academic institutions when large projects (or centers), closely tied to NIH objectives, are awarded to their institutions? What happens to the stability of institutions--and their ability to plan use of resources--when there are large fluctuations in NIH funding resulting from the political and fiscal decisions of the national budgetary process?

Communicating the results of biomedical research

Bringing research results to the scientist, the medical practitioner, the patient, and the general public requires continuing decisions on the bounds of the NIH role. Both the National Library of Medicine and the individual institutes play roles here, drawing on a wide range of mechanisms including support of nonprofit scientific publications, computerized bibliographic and data information systems, demonstration programs, workshops and symposia, and many communications directed to special segments of the biomedical community.

Most of the momentum in the scientist-scientist information flow comes from the internal peer review and publication systems of the various disciplines from which NIH-supported scientists are drawn. The feedback and evaluation mechanism of this system is essential to the growth of biomedical knowledge but NIH makes no effort to control it. A question here is how much NIH should directly support such vehicles of scientist-scientist flow as primary journals and data banks.

Scientist to physician. The problem of communicating the applications of biomedical research results to the practicing physician so that he can incorporate them into medical care and convey the benefits to patients is part of the larger, much discussed problem of diffusion of innovation. Diffusion of new medical technology requires different approaches from the management of biomedical research. In the past the agency has seen its role here as one of reaching the individual practitioner by means of disseminating information and training in new medical technology primarily to these physicians within the orbit of the major medical centers. Responsibility for further diffusion to practitioners, beyond active publication programs supported by all of the institutes, has been left to the major centers. Should this limited approach be changed? Should the NIH view its responsibilities as extending to all other centers and individual practitioners?

Currently, the most concentrated NIH efforts at diffusion to physicians are the Congressionally mandated extramural control and demonstration programs of the Cancer and Heart/Lung Institutes. The boundary problems between these programs and the disease control and demonstration responsibilities of such other HEW health agencies as ADAMHA, CDC, and HSA have already been referred to.

A problem in the flow of information from scientist to physician to patient arises in situations--such as the treatment of diabetes or hypertension--where effective treatment requires the informed participation of the patient. Here the benefit of an improved regimen developed through biomedical research may not be realizable without further behavioral research on ways of enlisting the cooperation of the patient. A twofold question arises: how far should NIH go in research on the delivery of health services when the Bureau of Health Services Research in the Health Resources Administration is the organizational locus, among the Health agencies, for this responsibility? To the extent that NIH supports work on the problems of health care delivery, how can the assistance of behavioral scientists be enlisted more systematically and explicitly than it has been in the past?

An important question in the scientist to public flow of information is how much into the public health prevention and protection area NIH should move. Despite mission assignments to other Health agencies, there is considerable pressure on the NIH to take direct steps to make the results of research immediately available to the citizen who, in effect, has already paid for them. But, public health education (for example, on the relationship between smoking and lung cancer) can be a costly and diffuse undertaking, with results not easily identified.

Postscript: Priority setting at NIH

The major organization and procedures for biomedical research policy formulation and implementation at NIH have been described. This process can be somewhat amplified and restated in terms of the central problem of public management--priority setting.

1. Priority setting at NIH is an interactive process within a multi-dimensional network. It involves feedback of information, ideas, and decisions both between and within institute programs, between institutes and OD/NIH, between NIH program planners and active biomedical scientists, and between NIH as a whole and executive, legislative, and public forces.

2. Priorities are generated and constraints imposed by, (a) political forces that design certain priorities into the categorical organization and charter of the institutes, based on public perceptions of the humanitarian, social, and economic significance of health problems, (b) technical forces which dictate that planning the achievement of practical health goals depends on prior accumulation of the necessary basic knowledge, and (c) the need to capitalize on the gathering momentum of knowledge-production in certain phases of the research process through selecting for investment areas that show, at the time, the greatest promise of yielding returns.

3. Operationally, these conditions are reflected in a series of continuing activities:

    a. The Executive and the Congress set the broad goals and boundaries for NIH research.

    b. NIH staff, using a range of advisory mechanisms, plan the support of assigned goals and establish relative priorities for allocation of resources. These attempt to take cognizance of the joint problem of social and economic significance and the constraints of existing knowledge.

    c. Plans are translated into action as resources are distributed to programs and to individual researchers.

    d. Staff evaluate progress toward achievement of NIH knowledge objectives and act on these evaluations in drawing up the proposed budget.

e. In the light of past experience and anticipated needs and opportunities, staff at all levels reassess and alter priorities for the coming year.